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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,951	11/27/2000	Charles E. Weeks	HOLISED.033A	6317

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HOLLIS-EDEN PHARMACEUTICALS, INC.  
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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/554,951

Applicant(s)

WEEKS, CHARLES E.

Examiner

San-ming Hui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11,22-29,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11,22-29,31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Upon reconsideration, Applicant's after-final amendment filed December 18, 2002 have been entered.

The outstanding rejections under 35 USC 112 and 103 are withdrawn in view of the remarks and amendments filed December 18, 2002.

The outstanding objection is withdrawn in view of the amendments filed December 18, 2002.

#### New ground of rejection

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 22-29 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant case, the instant specification fails to provide information to one of skilled in the art to practice the method of preventing arthritis without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400

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(CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The breadth of the claim is so broad that it encompasses the method of preventing every kinds of arthritic disorder. Merck Manual (The Merck Manual of Diagnosis and Therapy, 16<sup>th</sup>. ed., 1992, pages 1293-1315, 1326-1327, 1338-1343, and 1369-1371) teaches that certain kinds of arthritis are autoimmune related. Some of the arthritis are infection related, and osteoarthritis is degenerative disorders. It is well-known in the state of the art that the term "arthritis" encompasses so many different diseases from various origins and caused by different etiologies (e.g., multifactoral involving genetic, age, sex, and environmental) (See pages 1294-1295 of Merck Manual). The current known treatments of these disorders depends on the patient populations and the severity of the disorders. Moreover, treatments are mostly symptomatic (See page 1295, Treatment Section). Thus, it is clear from the evidence of

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the Merck Manual that the ability to treat and or prevent arthritis is highly unpredictable and has met with very little success. Applicants have not provided any convincing evidence such as working examples that their claimed invention is indeed useful as preventive for arthritis and have not provided sufficient guidance to allow one skilled in the art to select patient, without arthritic disorders and otherwise healthy, to receive the herein claimed treatment for the prevention of arthritis. The instant specification fails to provide information to one of skilled in the art to practice the claimed invention without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-3, 7, 11, 22, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lardy (US Patent 5,585,371) in view of Merck Manual, 16<sup>th</sup> ed., 1992, pages 1342-1343.

Lardy teaches that  $\Delta^5$ -androstene-3 $\beta$ -ol-7, 17-dione (7-oxo-DHEA), can enhance the immunological activity and treat infection caused by virus, bacteria, fungus, veroid and prion (See the abstract and Example V, also claims 1-4). Lardy also teaches the route administering the DHEA compounds as oral, subcutaneous, transdermal or nasal routes of administration (See col. 3, lines 46-51).

Lardy does not expressly teach 7-oxo-DHEA as useful in a method to treat arthritis such as infectious arthritis.

Merck Manual teaches infectious arthritis is resulting from infection of the synovial tissues with infectious agents and bacteria being the most often etiologic agents (See page 1342). Merck Manual also teaches infectious arthritis may be treated with anti-bacterial agents (See page 1343, Treatment Section).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 7-oxo-DHEA in a method of treating infectious arthritis.

One of ordinary skill in the art would have been motivated to employ 7-oxo-DHEA in a method of treating infectious arthritis. It is known that 7-oxo-DHEA is useful in treating infection caused by bacteria, virus, and fungus. It is also known that infectious arthritis is a form of arthritis resulted from infection of the synovial tissues with infectious agents and can be treated with anti-bacterial agents. Therefore, employing anti-

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bacterial agent, such as 7-oxo-DHEA, in the method of treating infectious arthritis would have been reasonably expected to be effective, absent evidence to the contrary.

***Response to Arguments***

Applicant's arguments with respect to claims 1-11, 22-29, 31, and 32 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

The method of treating rheumatoid arthritis, osteoarthritis, and fibromyalgia employing 7-oxo-DHEA is not taught or fairly suggested by the cited prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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San-ming Hui  
August 8, 2003



SREENI PADMANABHAN  
PRIMARY EXAMINER

8/08/03